

**REMARKS****Amendments to the Claims**

Claims 16-21 and 36-44 are pending. The Applicant respectfully asks the Examiner to replace all prior versions and listings of claims in the present application with the listing of claims currently provided. Claims 16, 17, 20 and 39 were amended. Claim 45 is new. The Applicant hereby states that all amendments do not add new subject matter to the specification.

Amendment support for Claim 16 can be found at, e.g., pg. 26, lines 27-30.

Amendment support for Claim 20 can be found at, e.g., pg. 28, lines 4-19.

Amendment support for Claim 39 can be found at, e.g., pg. 26, lines 27-30.

**Rejection Pursuant to 35 U.S.C. § 102(a) Anticipation**

The Examiner has rejected Claims 16, 17, 20, 21, 39, 40 and 44 as allegedly being anticipated pursuant to 35 U.S.C. § 102(a) by Herbert K. Graham, *Methods and Compositions for the Treatment of Cerebral Palsy*, U.S. Patent No. 6,939,852 (Sep. 6, 2005), hereafter “the Graham patent.” The Examiner contends that the Graham patent teaches “a pharmaceutical composition comprising a botulinum toxin A incorporated into a polymetric matrix of a suitable carrier and formed into an adhesive patch . . .” See, pg. 3, ¶ 2, lines 1-3, February 8, 2007 Office Action. The Applicant respectfully asks for reconsideration pursuant to 37 C.F.R. § 1.111.

According to MPEP § 2131, for a reference to anticipated a pending claim, that reference must teach each and every element of the pending claim.

Currently amended Claims 16, 17, 39, 440 and 44 are directed in part to a transdermal patch comprising a pharmaceutical composition and an adhesion layer “wherein the pharmaceutical composition is incorporated into the adhesive layer.” The Graham patent does not anticipate

the presently claimed transdermal patch because this patent teaches that the pharmaceutical composition is incorporated into a polymeric carrier and not directly into the adhesive layer. The present specification discusses both of these incorporation methods at pg. 26, lines 25-30, where it states:

The neurotoxin may be incorporated into a polymeric matrix that stabilizes the neurotoxin, and permits the neurotoxin to diffuse from the matrix and the patch. The neurotoxin may also be incorporated into the adhesive layer of the patch so that once the patch is applied to the skin, the neurotoxin may diffuse through the skin.

The Graham patent discloses the former incorporation method, whereas the transdermal patch of Claims 16, 17, 39, 40 and 44 are directed towards the later incorporation method. As such, the transdermal patch of the Graham patent does not possess the same material structure and functional characteristics of the presently claimed transdermal patch because it does not disclose an incorporation method where a pharmaceutical composition is incorporated into the adhesive layer. Thus, the Graham patent does not read on the presently claimed transdermal patch and the Applicant respectfully requests withdrawal of the 35 U.S.C. § 102(a) rejection against Claims 16, 17, 39, 440 and 44.

Currently amended Claims 20 and 21 are directed in part to a transdermal patch comprising a depot comprising a plurality of wells containing a pharmaceutical composition and an adhesion layer. The Graham patent does not anticipate the presently claimed transdermal patch because this patent teaches that the pharmaceutical composition is incorporated into a polymeric carrier and not into wells. The present specification contrasts an incorporation method using a polymeric matrix with a release method using wells at pg. 26, lines 25-30 where it states “[a]lternatively [to a polymeric matrix], the neurotoxin may be provided in one or more wells or pockets disposed near the surface of the patch that will contact the skin.” As such, the transdermal patch of the Graham patent does not possess the same material structure and functional characteristics of the presently claimed transdermal patch of Claims 20 and 21 because it does not disclose a patch comprising wells. Thus, the Graham patent does not read on the presently claimed transdermal patch and the Applicant respectfully requests withdrawal of the 35 U.S.C. § 102(a) rejection against Claims 20 and 21.

Therefore, the Applicant respectfully submits that the pending claims are not anticipated by the Graham patent and respectfully requests withdrawal of the 35 U.S.C. §102(e) anticipation rejection for Claims 16, 17, 20, 21, 39, 40 and 44.

### **Rejection Pursuant to 35 U.S.C. § 103(a) Obviousness**

#### **I. Graham in view of Yuzhakov.**

The Examiner has rejected Claims 18 and 19 as allegedly being obvious pursuant to 35 U.S.C. § 103(a) over the Graham patent in view of Vadim V. Yuzhakov et al., *Microneedle apparatus Used for Marking Skin and for Dispensing Semi-Permanent Subcutaneous Makeup*, U.S. Patent No.6,565,532 (May 20, 2003), hereafter “the Yuzhakov patent.” The Examiner contends that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the transdermal patch as taught by the Graham patent to include the needle array as taught by the Yuzhakov patent because the Yuzhakov patent teaches “that the invention is projected or penetrates the stratum corneum to transfer actives or skin support structures to the epidermis.” See pg. 5, ¶ 2, lines 1-8, February 8, 2007 Office Action. The Applicant respectfully asks for reconsideration pursuant to 37 C.F.R. § 1.111.

According to MPEP § 2143.03, “To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” Citing, In re Royka, 490 F.2d 981, 180 USPQ 580 (C.C.P.A. 1974).

Claims 18 and 19 are dependent on Claim 16. As discussed above, currently amended Claim 16 is directed, in part, to a transdermal patch comprising a pharmaceutical composition and an adhesion layer “wherein the pharmaceutical composition is incorporated into the adhesive layer.”

As discussed above, the Graham patent teaches a transdermal patch that a pharmaceutical composition is incorporated into a polymeric carrier. However, the Graham patent is

completely silent with respect to a teaching of an incorporation method where a pharmaceutical composition is incorporated into the adhesive layer as presently claimed. The Yuzhakov patent also fails to teach the incorporation method presently claimed. As such, the Graham patent in view of the Yuzhakov patent would not make the presently claimed transdermal patch obvious because neither reference alone or in combination teach or suggest the use of an incorporation method where a pharmaceutical composition is incorporated into the adhesive layer as presently claimed. Because both references fail to teach or suggest this claim limitation a *prima facie* case of obviousness cannot be made. Therefore, the Applicant respectfully requests withdrawal of the 35 U.S.C. § 103(a) obviousness rejection for Claims 18 and 19.

## ***II. Graham in view of Cevc.***

The Examiner has rejected Claims 36-38 and 41-43 as allegedly being obvious pursuant to 35 U.S.C. § 103(a) over the Graham patent in view of Gregor Cevc, *Preparation for the Application of Agents in Mini-Droplets*, U.S. Patent No. 6,165,500 (Dec. 26, 2000), hereafter “the Cevc patent.” The Examiner contends that it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the transdermal patch as taught by the Graham patent to incorporate the transfersomes as taught by the Cevc patent because the Cevc patent teaches “compositions that comprise transfersomes ranging in concentration from 0.1 to 99% of the total composition, the use of edge active substances used in the transfersomes . . . and the use of buffers.” See pg. 7, ¶ 2, lines 1-9, February 8, 2007 Office Action. The Applicant respectfully asks for reconsideration pursuant to 37 C.F.R. § 1.111.

According to MPEP § 2143.03, “To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” Citing, *In re Royka*, 490 F.2d 981, 180 USPQ 580 (C.C.P.A. 1974).

Claims 36-38 are dependent on Claim 16 whereas Claims 41-43 are dependent on Claim 39. As discussed above, currently amended Claims 16 and 39 are directed, in part, to a

transdermal patch comprising a pharmaceutical composition and an adhesion layer "wherein the pharmaceutical composition is incorporated into the adhesive layer."

As discussed above, the Graham patent teaches a transdermal patch that a pharmaceutical composition is incorporated into a polymeric carrier. However, the Graham patent is completely silent with respect to a teaching of an incorporation method where a pharmaceutical composition is incorporated into the adhesive layer as presently claimed. The Cevc patent also fails to teach the incorporation method presently claimed. As such, the Graham patent in view of the Cevc patent would not make the presently claimed transdermal patch obvious because neither reference alone or in combination teach or suggest the use of an incorporation method where a pharmaceutical composition is incorporated into the adhesive layer as presently claimed. Because both references fail to teach or suggest this claim limitation a *prima facie* case of obviousness cannot be made. Therefore, the Applicant respectfully requests withdrawal of the 35 U.S.C. § 103(a) obviousness rejection for Claims 36-38 and 41-43.

## **CONCLUSION**

For the above reasons the Applicant respectfully submits that the claims are in condition for allowance, and the Applicant respectfully urges the Examiner to issue a Notice to that effect. Should there be any questions, the Examiner is invited to call the undersigned agent.

Please use Deposit Account 01-0885 for the payment of any extension of time fees pursuant to 37 C.F.R. § 1.136 or any other fees due in connection with the current response.

Respectfully submitted,

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